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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,841	05/22/2001	Karla Kirkegaard	STAN-193	8970

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,841	KIRKEGAARD ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1 and 4-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/2003 and06/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Response to restriction requirement filed 12/01/2003 is acknowledged. Applicant elected, with traverse, Group I, claims 2(in part) and 3. Applicant argues that as the term "pharmacophore" is generic to particular pharmacophores of Groups IV-VI, each of these groups should be included in examination. Examiner disagrees. The claims are set in such way that part of the claims (claims 2-6) are drawn to products defined by the structure of the receptor, while other claims (claims 8-12) are drawn to products defined by the structure of the ligand. A reference teaching a peptide of claim 8, for example, will not necessarily teach the pharmacophore of claim 2 (or 4) because claim 8 is not drawn to a peptide that binds to particular location of RNA-polymerase. Conversely, a reference teaching an agent that binds to a particular location (e.g., as defined in claim 2) will not necessarily teach the polypeptide pharmacophore of claim The restriction requirement is deemed proper and is therefore made FINAL. Claims 4-12, 17-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 4-12, 17-24 is requested.

Subject matter of Group I, namely a pharmacophore that binds to surface defined by residues 342 and 349 is under consideration. Linking claims 1,13-16 are withdrawn from consideration and will be addressed after the elected subject matter is deemed allowable. Claim 2 is addressed to the extent it reads on the elected subject matter.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, the term "binding to a surface structurally defined by ... residues 342 and 349" is a relative term which renders the claim indefinite. It is not clear under which conditions the residues (that are flexible) identify a flat surface; furthermore, which part of the residues serve as "identifier" for the surface.

Second, the term "surface identified by ...corresponding positions thereof" is even more indefinite as the term "corresponding positions thereof" is not defined and thus the surface to which the pharmacophore is supposed to bind is also undefined.

Third, it is not clear whether the pharmacophore is supposed to bind the indicated the indicated residues themselves, or the surface defined thereby.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2,3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a pharmacophore that binds to surface defined by residues 342 and 349 of RNA-polymerase. Specification does not describe any pharmacophore that binds, specifically, to said residues of RNA-polymerase. Example 10 (pages 47-49) does describe peptide SEQ ID No. 5 which does disrupt RNA-polymerase functions. However, there is no evidence that said polypeptide belongs to the genus as claimed, i.e, that it does bind to the specified residues 342 and 349 of RNA-polymerase.

With respect to adequate disclosure of the scope of the presently claimed generic, applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* U.S. Court of Appeals Federal Circuit (CA FC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997 No. 96-1175 regarding disclosure. For adequate disclosure, like enablement, requires *representative examples* which provide reasonable assurance to one skilled in the art that the compounds falling within the scope, both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention*. See In re Riat et al. (CCPA 1964) 327 F2d

685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure.

Unlike *Lilly*, applicant does not have a single example of a peptide within the scope of the presently claimed invention, i.e. that binds to surface defined by residues 342 and 349 of RNA-polymerase and thus does not provide even a single species in support of a potentially broad generic of different and nonexemplified products.

Like Lilly, applicant asserts that there is a means of obtaining these peptides; however, this is not relevant to the disclosure requirement in which the applicant must demonstrate possession of the claimed scope at the time of filing.

Accordingly, it is clear that applicant has not demonstrated possession of the scope of the presently claimed subject matter. In fact applicant, in the present case, unlike the Lilly case, *has failed to demonstrate even a single species within the scope of the presently claimed generic.* Accordingly, applicant is not in possession of the presently claimed invention.

Claims 2,3 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabling for making of the product as claimed. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to a pharmacophore that binds to a surface defined by residues 342 and 349 of RNA-polymerase. Such claim language means that the pharmacophore binds not particular residues of RNA polymerase, but rather binds a surface "defined" by the residues. As definition of the term "surface structurally defined by ... residues 342 and 349" is not clear (see rejection under 35 U.S.C. 112, second paragraph, above), it is not clear how to make products that satisfy the claimed structural limitations. Specification reviews known methods of drug modeling (pages 14-19); however, this description does not address the issue of undefined structure to which pharmacophore is supposed to bind. Further, specification (example 10, pages 47-49) describes design of peptide SEQ ID No. 5 which does disrupt RNA-polymerase functions. However, there is no evidence that said polypeptide belongs to the genus as claimed, i.e, that it does bind to the specified residues 342 and 349 of RNA-polymerase. In view of the above, it is the Examiners position that with the insufficient guidance and working examples, one skilled in the art could not make the invention with the claimed breadth without an undue amount of experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2,3 are rejected under 35 U.S.C. 102(b) as anticipated by Sergio et al. (US Patent 6,492,423).

The instant claims are drawntoo a pharmacophore that binds to a surface defined by residues 342 and 349 of RNA-dependent RNA-polymerase. No structure requirements are present in the claims.

Sergio et al teaches diketoacids that inhibit viral polymerases, RNA-dependent RNA-polymerase in particular (col. 6, line 13-14) . As the referenced diketoacids inhibit RNA-dependent RNA-polymerase, they are inherently capable of binding to the RNA-dependent RNA-polymerase. Examiner assumes that, in the absence of evidence to the contrary, the referenced inhibitors bind to the RNA-dependent RNA-polymerase in the manner required by the instant claims. Since the Office does not have the facilities for examining and comparing applicants' pharmacophore with the pharmacophore of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the pharmacophore of the prior art does not bind to the same " surface

defined by residues 342 and 349 of RNA-dependent RNA-polymerase"). See *In re* Best, 562 F.d. 1252, 195 USPQ 430 (CCPA 1977) and *In re* Fitzgerald et al., 205 USPQ 594. in particular in particularli that inhibit viral polymerases, RNA-dependent RNA-polymerase

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

March 11, 2004

mlb